



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

July 22, 2013

MEMORANDUM

Subject: Efficacy Review for EPA File Symbol 53735-RU, Spa Chlorine Disinfectant
DP Barcode: 412069

From: Marcus Rindal, Microbiologist *MR 7.22.13*
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Applicant: King Technology
530 11th Avenue, South
Hopkins, MN 55343

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
1,3-dichloro-5, 5-Dimethylhydantoin.....	81.1%
1, 3-dichloro-5-ethyl-5-methylhydantoin.....	16.1%
<u>Other Ingredients</u>	<u>2.8%</u>
Total.....	100.0%

I. BACKGROUND

The product, Spa Chlorine Disinfectant (EPA File Symbol 53735-RU), is a new end-use product. Technology Sciences Group, Inc., on behalf of King Technology, Inc., has requested to register the product for use as a sanitizer/disinfectant for the treatment of spas and hot tubs. The product is intended to be used in conjunction with the Pool Frog Mineral Reservoir (alternate name: Spa Frog Mineral Cartridge, EPA Reg. No. 53735-11) which contains silver chloride as the active ingredient. The new product, Spa Chlorine Disinfectant, is intended to provide an alternate chlorine source to be the oxidizer in the two-part mineral system. This product is a 100% re-pack of [REDACTED]

[REDACTED]. Due to the spa use on the product, an Experimental Use Permit was issued for this product on April 28, 2009, and an effectiveness study was performed and completed on February 5, 2013.

Data supporting the efficacy of Spa Frog Mineral Cartridge for pools (with chlorine and bromine) and spas (with bromine) has been submitted and used to support registration (MRIDs 461240-01, 468869-01, 468869-02). The study described here is an in-field test intended to substantiate the effectiveness of Spa Chlorine Disinfectant (consists of dichlorodimethylhydantoin, or DCDMH), when used with the Spa Frog Mineral Cartridge, a proprietary silver release system. The study was designed to test the effectiveness of the combination system in controlling specific types of microorganisms under conditions where bathers are present. Basically, DCDMH acts as an alternative source of oxidant (free chlorine, generated by hydrolysis) that will be used with silver ions released by the Spa Frog Mineral Cartridge. The efficacy of the silver ion-oxidant combination has already been demonstrated by laboratory and field tests (MRIDs are listed above). This study was carried out under Experimental Use Permit EUP No. 53735-EUP-3 for the Spa Chlorine Disinfectant with the Spa Frog Mineral Cartridge. The EUP was initially granted by EPA on 28 April 2009, and reinstated on 18 January 2012, with the stipulation that the usability of proposed replacement methods for microbiological evaluation first be shown (Appendix 8). Further, the study complies with EPA Document DIS/TSS-12, "Efficacy Data Requirements for Swimming Pool Disinfectants," which was later incorporated into draft OCSPP Guideline 810.2600(e)(2): Disinfectants for Use in Water – Efficacy Data Recommendation, 11 May 2011. The final version of this OCSPP Guideline was issued on 19 June 2012. The submitted study was performed by 2 laboratories, King Technology, Inc. (530 11th Avenue South, Hopkins, MN, 55343) and MVTL Laboratories, Inc. (1126 N. Front St., New Ulm, MN, 56073).

The data package contained a letter from the applicant's representative to EPA (dated February 14, 2013), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-27 (Formulators' Exemption), Certification with Respect to Citation of Data, Data Matrix, Transmittal, Product Label, one study (MRID 490522-01), and Statement of Data Confidentiality Claims (indicating that information claimed as confidential has been removed to a confidential attachment).

II. USE DIRECTIONS

Product Description: Use this Spa Chlorine Disinfectant cartridge in either in the In-line Spa System or the Floating Spa System as a sanitizer with Spa Frog Mineral Cartridge. Together they make spa care a breeze with up to 75% (compared to the ANSI minimum recommended chlorine level of 2.0 ppm for a residential spa) less chlorine so the water feels softer and looks crystal clear with no smelly odors. Swimsuit colors stay bright and spa surfaces maintain their

brilliance longer.

Directions for Use: Ensure all spa equipment is working properly. The pump and filter should be operated for at least 3 hours per day. Clean filter following manufacturer's directions. Fill spa with fresh water and balance the water according to the water balance guidelines with pH between 7.2 – 7.8 and total alkalinity at 60 to 120 ppm. After balancing, establish a free chlorine residual of 0.5 to 1.0 ppm in the spa with FROG Jump Start or an EPA approved spa shock following the directions for that product. When using other products as outlined in directions for this product, always follow directions on those products.

Setting the Output: The SPA CHLORINE DISINFECTANT is prefilled and adjustable to meet the needs of each spa use. Typically In-Line System users will begin on setting # while Floating System users will begin on setting # and adjust up or down from there. Hold the bottom and turn the top of the cartridge until the correct number appears in the setting window. See the setting chart in the manual for best results.

Then use SPA CHLORINE DISINFECTANT into one of the following system{s}:

- **The In-line Mineral Spa System:** Open cap of Inline System, push down and turn cartridge holder counter-clockwise to unlock. Pull holder out. Snap cartridge into lower/bottom section (marked "Bromine or Chlorine Only"). Make sure to line up indent on cartridge with raised line on holder. After cartridge is snapped in, replace holder by lining up arrow on holder with arrow on system lip, push down and lock in place. Replace cap.
- **The Floating Mineral Spa System:** Push the cartridge into the bottom opening of the Floating Spa System and place entire system in the spa water. When using the Spa Frog Mineral Cartridge, maintain a free chlorine level of 0.5 – 1.0 ppm. Initially monitor free chlorine levels daily and adjust the cartridge up or down by one setting per day until the desired chlorine level is achieved. Adjusting to a higher setting will increase the chlorine output while a lower setting will decrease it. When empty follow disposal instructions and replace with a new SPA CHLORINE DISINFECTANT.

Shock the spa or add clarifier occasionally if the water should become cloudy. With SPA CHLORINE DISINFECTANT less shocking is required because of the chlorine bank (measured as total chlorine) that is ready to use when needed.

REENTRY into treated spas is prohibited above levels of 5 ppm available (free) chlorine as measured by a suitable test kit due to risk of bodily injury.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Waters in Swimming Pools, Spas, Hot Tubs, Whirlpools, and Jacuzzis – Confirmatory Field Testing

Swimming pool (and spa) water disinfection presents a unique combination of variables, including the number of swimmers/bathers, the frequency of use, the frequency with which the water is changed, general environmental conditions, and the type/degree of organic contamination of the water by the swimmers/bathers (e.g., suntan lotions and oils) and by various debris. As a result, both laboratory testing and confirmatory field testing are required.

Confirmatory field testing must take place in at least two swimming pools (or spas),

under an Experimental Use Permit, lasting for an entire swimming season (4 to 12 months). Reports must include at least the following data regarding the test pools:

- (i) The design of the pool, the recirculation and filter systems, and the water capacity;
- (ii) The daily bather load;
- (iii) The amount and identification of all chemicals added daily (specifying time, site and method);
- (iv) The range of chemical characteristics of the water, such as pH, nitrogenous substances, metals and hardness;
- (v) The physical characteristics of the water, including temperature and clarity, determined at least daily;
- (vi) Daily meteorological data, including air temperature, rainfall, and number of hours of sunlight for outdoor pools;
- (vii) Bacteriological monitoring should be conducted daily, in accordance with the suggested Ordinance and Regulations Covering Public Swimming Pools of the American Public Health Association. Water samples for bacteriological analysis should be taken on opposite sides of the pool in the shallow area and as remote as possible from the inlets, preferably at the midpoints between inlets. A minimum of 144 samples should be taken during the test period. Samples should be taken just below the surface of the water, and preferably at such times when the number of persons using the pool during the preceding hour has been at least 50% of the maximum bather load of the pool, and the number of persons in the pool water at the time the samples are collected is at least equal to 25% of the maximum bather load of the pool. Pertinent chemical characteristics of the pool water at the sampling site should be determined at the time of sampling;
- (viii) The concentration of the antimicrobial agent in the water monitored daily at the same time-intervals that the bacteriological assay samples are obtained;
- (ix) The method that the product user will employ for monitoring the level (ppm) of antimicrobial agent in the water

Field test results must show that 85% of the samples collected meet the following indices (i.e., or that not more than 15% of the samples collected fail the following indices): (1) The standard plate count at 35°C shall not exceed 200 colonies/1.0 mL; (2) The most probable number of coliform bacteria shall be less than 2.2 organisms/100.0 mL. When the membrane filter test is used, there shall be no more than 1.0 coliform organisms/50 mL; and (3) The most probable number of enterococcal organisms shall be less than 2.2 organisms/100.0 mL. When the membrane filter test is used, there shall be no more than 1.0 enterococcal organisms/50 mL.

IV. SUMMARY OF SUBMITTED STUDY

- 1. MRID 490522-01 "Effectiveness of a New Spa Disinfectant System: Dichlorodimethylhydantoin (DCDMH) and the *Spa Frog Mineral Cartridge*: In-Use Field Test," for *Spa Chlorine Disinfectant*, by John Hill. Study conducted by King Technology, Inc. and MVTL Laboratories, Inc. Study completion date – February 5, 2013. Laboratory Project Identification Number KTI-0703.**

A four-month in-field study of the efficacy of the *Spa Frog Mineral Cartridge* in combination with free chlorine from DCDMH (dichlorodimethylhydantoin, the active ingredient in *Spa Chlorine Disinfectant*) has been completed. The study was performed under EPA Experimental Use Permit No. 53735-EUP-3 in two spas located in Hopkins, Minnesota at the facilities of King Technology, Inc. (KTI). Bathers used each spa five days per week, with the exception of

holidays and summer business hours when work weeks alternated between four and five days. The water in each spa was not changed during the four-month study. Water in each spa was sampled regularly and analyzed chemically and microbiologically.

Study Spas: The spas were located in a testing facility at King Technology, Inc. (KTI), 530 11th Ave. South, Hopkins, MN 55343. The testing facility occupies 1360 square feet of a building totaling approximately 25,000 square feet. Air temperatures in the testing facility were maintained at nominally 70° (21.1°C) to 84° F (29.0°C) for the comfort of bathers. The ambient temperature was controlled through a dedicated air handling system that was separate from the rest of the building. Access to the Pool and Spa Room was limited to personnel directly involved in the study, through a keypad combination locking system.

- Spa 1: a 300-gallon Marquis brand spa, with dimensions of 84 in x 84 in x 35.5 in, and a water depth of approximately 25 inches without bathers. Spa 1 featured 35 jets and two pleated filter cartridges (Unicel Type 5CH-502), each having a filtration area of 50 square feet. Filter cartridges were replaced approximately midway through the study. Spa water was maintained between 101° F (38.1°C) to 104° F (39.8° C) and was circulated at least 2 hours daily. While bathers were in the spas, residual free chlorine levels were maintained between 0.2 and 1.43 ppm.
- Spa 2: a 550-gallon Jacuzzi brand spa, with dimensions of 94 in x 94 in x 38 in, with a water depth of approximately 27 inches without bathers. Spa 2 featured 43 jets and two pleated filter cartridges (Unicel Type 6CH960), each having a filter area of 52 square feet. Filter cartridges were replaced approximately midway through the study. Spa water was maintained between 99° F (37.3°C) to 104° F (40.2° C) and was circulated at least 2 hours daily. While bathers were in the spas, free chlorine levels were maintained between 0.2 and 1.51 ppm.

Source of Silver Ions: A case containing 12 exemplars of *Spa Frog Mineral Cartridge* (EPA Reg. No. 53735-11) was randomly selected from production inventories. The cartridges were manufactured on 05 December 2011 (Lot No. 2901 11L5) and prior to use were stored in a cool, dry location with controlled access. A *Spa Frog Mineral Cartridge* was installed in each spa on 05 April 2012, i.e. five days prior to use of the spas. Neither *Spa Frog Mineral Cartridge* was changed during the study.

Free Chlorine Source: The *Spa Chlorine Disinfectant* consists of DCDMH (dichlorodimethylhydantoin), and was used to maintain levels of free chlorine. The DCDMH used in the study had the trade name [REDACTED] [REDACTED] on 28 October 2011. A total of 14.06 kg was received (Lot No. K1436111). The DCDMH used was chemically identical to the product that will be sold as *Spa Chlorine Disinfectant*. For this study, granular DCDMH was transferred to unused plastic housings similar to those used to contain *Spa Frog Minerals* and *Spa Frog Bromine* products. Each housing contained about 100 g of DCDMH, and was recharged as necessary.

Procedure: Test spas were filled with fresh water on 03 April 2012, i.e., seven days prior to the initiation of the study. The water in each spa was balanced by addition of calcium chloride and sodium bisulfate to support label language. A *Spa Frog Mineral Cartridge* was installed in each test spa by allowing it to free float at the water surface, according to label directions. For this study a dial setting of 6 was used for each *Spa Frog Mineral Cartridge*. The dial setting controls the contact of spa water with the contents of the *Spa Frog Mineral Cartridge*. Test Spas 1 and 2 had volumes of approximately 300 and 550 gallons, respectively. The spas were operated normally, in compliance with accepted industry practices and relevant labeling for all products except DCDMH, which was being evaluated in the study. The temperature of water in each spa

was maintained between 99° F (37.3° C) and 104° F (40.2° C). Bathers participating in the study were volunteer KTI employees who agreed to comply with study requirements (provided to each). Bathers were provided with clean swimsuits, robes, sandals and towels, and each was required to take a soapy shower before entering one or the other spa. Bathers used both spas four to five days per week, excluding holidays and other occasional days specified by the Study Director or Study Coordinator. On each day of use, two bathers used the 300-gallon spa, and four bathers used the 550-gallon spa over a one hour period. Each use consisted of two 15-minute intervals in the spa, separated by 7 to 15 minutes outside the spa (for bather safety - it was not recommended that a user remain in an operating spa for more than 15 minutes at one time). Samples of water were collected from each spa at about 11:30 a.m. (labeled by date, spa number, and "AM"), and about 12:00 p.m. (labeled by date, spa number, and "PM"). Each sample was collected when the spa was occupied, as above.

Water Sampling and Analysis: Spa water was sampled as described below. A number of chemical and microbiological tests were carried out, following regular schedules. The main test methods, including the reagents and equipment used, are described in separate appendices. Daily measurements were made of pH (electrometric with glass electrode), turbidity (Hach turbidimeter), air and water temperature (glass and digital thermometers), and bather load (count). Total silver was determined weekly. Iron, copper, alkalinity, nitrogen ammonia, calcium hardness, and chloride levels were determined monthly. Samples for routine tests were drawn approximately 6 inches below the spa water surface. The collection site for water samples alternated between opposite sides of the spas. Free chlorine concentrations were measured at KTI using a Hach DR/4000V Spectrophotometer (Loveland, CO) programmed for free and total chlorine analysis (Hach Program 1450 for Method 8021) utilizing DPD Free Chlorine Reagent (Hach Cat. No. 21055-28, Lot No. A1273, Exp. Date Sep 2016). The entire method was validated prior to use, and calibration checks were performed throughout the study. Spa water sample samples for microbiological analyses were collected in sterile 100-mL water sampling bags containing sodium thiosulfate (Whirl-pak Thio-bag, product # 99100014). Each filled bag was assigned a unique identifier (spa number, date and time of collection) and placed in a labeled ice-chilled cooler (separate coolers for each spa). Each bag was maintained at 4° (± 2) C until processing at KTI, which generally occurred within two hours of filling. Bacterial counts were determined at KTI following the methods (heterotrophic bacteria, *Enterococcus* species, fecal coliforms, respectively). All measurements were made in triplicate, i.e. with three separate portions of sampled water. Each count value reported below is the mean of the three separate measurements. Water samples to be analyzed at MVTL Laboratories, Inc. for metals or inorganic species were collected in polycarbonate bottles provided by the laboratory. Some bottles contained preservatives, depending on the analyte. Water samples requiring determination of silver, iron, calcium hardness, or copper were preserved with nitric acid, and those requiring analysis for ammonia and nitrogen were preserved with sulfuric acid. Water samples to be analyzed for alkalinity and chloride were not preserved. Samples for MVTL were immediately cooled and transported cold to the analytical lab. All analyses at MVTL occurred within the maximum holding times (specific to the methods used). The bather load (number of human bathers) for each spa was recorded in dedicated logbooks. Records include time each bather spent in the spa and the associated break times. Bathers were required to sign in and out of the logbook, with their participation verified by study personnel or spa facility support.

V. RESULTS

The main attributes of the spas are noted in the sections below. In general, one to two days were required for each spa to reach steady-state conditions. The pH of each spa started out

somewhat elevated, i.e. essentially identical to that of the domestic water used to fill the spas. The levels of total silver in each spa increased from zero, when the *Spa Frog Mineral Cartridge* was installed, to a relatively constant level of about 10 to 20 ppb. All data collected (except as noted below) were taken to be usable in delineating the antimicrobial efficacy of the test system.

Air (Ambient) Temperature: The air temperature at Spa 1 ranged from 22.8° C (73.1°F) to 28.4° C (83.1 °F), with an overall mean of 25.3° C (77.4°F). The same average air temperature is shown for Spa 2 because the test spas were adjacent to one another in the same room. These temperatures were typical of indoor temperatures for the state of Minnesota from April to August.

Spa Chemical Treatments: During the study each spa required only two shock treatments, utilizing sodium dichloro-striazinetrione, with no other additions of oxidizers besides DCDMH (released from cartridges).

Spa pH: The average pH for Spa 1 was 7.51. Spa 2 showed an average pH of 7.40. Both averages are close to the center of the range generally considered acceptable for spas. In general the pH of each spa was adjusted as necessary. Both spas showed slow changes in pH with time, but no pH reading exceeded pH 8.05, the pH of the domestic water used to fill the spas.

Water Turbidity: Spa 1 had an average turbidity of 0.31 NTU and Spa 2, 0.40 NTU. Turbidity was not a parameter to be controlled during the study as long as it remained below 1.0 NTU. However, the average turbidity in both spas was within the range commonly encountered in spas.

Water Temperature: The average water temperatures for Spa 1 and Spa 2 were 38.6° C and 38.7° C, respectively, corresponding to 101.5° F and 101.7° F.

Levels of Free Chlorine: The level of free chlorine in Spa 1 on Day 1 (10 April 2012) amounted to about 0.2 ppm, but then increased. On all subsequent days the level was 0.29 ppm or greater, with a maximum of 1.43 ppm. The average monthly level for Spa 1 was 0.68 ppm. As noted below, control of all organisms was observed even at low free chlorine concentrations. The level of free chlorine in Spa 2 on Day 1 (10 April 2012) also amounted to about 0.2 ppm, but then increased. On all subsequent days the level was 0.34 ppm or greater, with a maximum of 1.51 ppm. The average monthly level for Spa 2 was 0.80 ppm. As noted below, control of all organisms was again observed even at low free chlorine concentrations.

Bather Load: Bathers used the spas 78 days, either four or five days per week. The study design specified a bather load of two individuals for Spa 1 and four individuals for Spa 2. These loadings were achieved over one hour, approximately starting at 11:05 AM and ending at 12:05 PM. Each bather soaked in the spa for a total of 30 minutes, i.e. two 15-minute intervals separated by a 7 to 15-minute rest interval to reduce the potential for bathers to become overheated. All water samples were collected with bathers in spas, with the exception of the weekly and monthly water samples for chemical analysis by MVTL.

Other Chemical Parameters: Parameters that were monitored monthly included: iron, copper, calcium hardness, alkalinity, nitrogen as ammonia, and chloride. These parameters were monitored to fulfill the requirements of DIS/TSS-12, "Efficacy Data Requirements for Swimming Pool Disinfectants," an EPA Document. Some of the parameters (levels of iron and copper) were affected by the quality of (domestic) water used to fill the spas. Others (levels of alkalinity

and calcium) were affected partly by the quality of domestic water and partly through the addition of standard spa treatment chemicals. The *Spa Frog Mineral Cartridge* formula acts as a source of silver ions and also a source of calcium ions and carbonate ions, through solubility. Concentrations of nitrogen as ammonia remained low in both spas throughout the study. In Spa 1, the ammonia concentration was below the reporting limit (0.16 ppm) until the last month where it rose to 0.37 ppm, i.e., slightly above the reporting limit. Likewise, in Spa 2, ammonia concentrations remained at or near the reporting limit of 0.16 ppm then rose to 0.28 ppm by the end of the study, i.e., close to the reporting limit for nitrogen as ammonia. The low level of ammonia nitrogen accumulation was surprising considering the heavy use of the spas and that each was shocked only twice during the 4-month study. Shock treatments to remove accumulated organic wastes and chloramines were performed as often as once after each heavy use of a spa. The rise in nitrogen as ammonia concentration coincided with the addition of sodium dichloro-s-triazinetriene shocking agent.

Levels of Bacteria: From EPA Directive DIS/TSS-12, at least 144 water samples were to be examined for levels of microorganisms, using approved evaluation methods. Not more than 15% of the samples could fail to meet the threshold limits of the relevant microbiological standard. The threshold limits specify that the sampled water can contain no more than a) 200 colony forming units (CFU) of heterotrophic bacteria per 1.0 mL, or b) one CFU of *Enterococcus* sp. per 50 mL, or c) one CFU of *Escherichia coli* per 50 mL. In all, 156 water samples for microbiological examination were drawn from each spa. All 156 samples were evaluated for levels of heterotrophic bacteria, *E. coli*, and enterococci. Two results from each spa (15 June 2012) for enterococci were rejected because an interruption of power to the incubator caused a deviation in incubation temperature. No water sample from either spa contained detectable levels of either *E. coli* or enterococci. A total of 156 water samples from Spa 1 were examined for levels of heterotrophic microorganisms. Of these, only 1.28% (two samples) exceeded any of the allowable CFU thresholds, so the DIS/TSS-12 criteria were satisfied. Likewise, Spa 2 also met the DIS/TSS-12 criteria. For Spa 2, 0.64% (one of 156 samples) exceeded the allowable CFU threshold. The levels of free chlorine maintained in this study ranged from about 0.2 to about 1.5 ppm, with averages of 0.68 ppm in Spa 1 and 0.80 ppm in Spa 2. In all cases the DSS/TSS-12 criteria were satisfied, so the study results clearly demonstrate that the *Spa Frog Mineral Cartridge* used with free chlorine from DCDMH is an effective spa disinfectant. This finding agrees with those of previous field studies (see above, Background and Study Objectives, MRIDs 454488-02, 461240-01, 468869-01 and 468869-02). The study results show clearly that the *Spa Frog Mineral Cartridge* is efficacious as a spa disinfectant with DCDMH when free chlorine levels of at least 0.5 ppm are maintained.

Levels of Silver Ions: Silver ions in combination with low levels of free chlorine from DCDMH represented the biocidal agent under evaluation in this study. The silver ions originated from the *Spa Frog Mineral Cartridge*, which contained solid silver chloride (AgCl) distributed over a porous matrix. For Spa 1, the monthly average level of total silver ranged between 11.5 ppb and 16.2 ppb, and for Spa 2, between 8.8 ppb and 13.4 ppb. The lowest mean level of chloride ion found (156 ppm for Spa 2) leads to a predicted equilibrium maximum concentration of silver ions of 4.34 ppb. The mean levels of total silver found in the spa water were about 13.6 ppb and 11.3 ppb for Spa 1 and Spa 2, respectively. These levels exceed the predicted maximum concentrations of silver ions by factors of about 2.2. The observed excess of the measured levels of total silver over the maximum predicted equilibrium concentration of silver ions was thought to originate from two possible causes. First, it was conceivable that tiny crystals of AgCl, in addition to soluble species including silver ions, contributed to the total silver concentration. Second, it is possible that silver existed in more than one soluble form, that is, in a soluble form (or forms) in addition to hydrated silver ions. Hydantoins like DCDMH are suspected of forming

complexes with some metals, and it is possible that a soluble complex formed between silver ions and DCDMH or its degradation product dimethylhydantoin. Any contribution from a soluble complex would be included in levels measured for total silver. In any case, both (a) tiny crystals of silver chloride, and (b) soluble complexes of silver ions were at all times in equilibrium with silver ions, and in fact provided reservoirs for silver ions. If silver ions were consumed (irreversibly precipitated or bound) during the process of disinfection, the reservoirs provided (by dissociation) additional silver ions, to maintain the overall chemical equilibria. Levels of total silver stabilized in the range of 11.3 to 13.6 ppb in both spas. In addition, the *Spa Frog Mineral Cartridge* used with free chlorine in the range of 0.2 to 1.5 ppm was an effective pool disinfectant. Clearly the levels of total silver were sufficient for the intended purpose, whether the silver was present as silver ions, silver chloride crystals, or as complexed silver ions. The latter were tied together through the underlying equilibria.

VI. CONCLUSIONS

The submitted field test data (MRID No. 490522-01) **do not** support the use of the product, Spa Chlorine Disinfectant, as a spa disinfectant when used in conjunction with Spa Frog Mineral Cartridge with a concentration ≥ 0.5 ppm free chlorine. Field test results showed that the standard plate count exceeded 200 colonies/1.0 mL in <15% of the samples collected; however, the tested concentrations do not support a 0.5 ppm disinfection claim.

During bathing intervals, the mean level of free chlorine in Spa 1 (300 gal.) amounted to 0.68 ppm. In all, 156 water samples from Spa 1 were examined microbiologically to meet the DIS/TSS-12 minimum of 144 samples. Of these, 1.28% (i.e., two samples) failed to meet DIS/TSS-12 microbiology requirements for total heterotrophic plate count, compared to an allowable failure rate of 15%. No spa water samples contained detectable levels of either enterococci or *E. coli*. The corresponding mean level of free chlorine in Spa 2 (550 gal.) was 0.80 ppm. In all, 156 water samples from Spa 2 were examined microbiologically to meet DIS/TSS-12 requirements of 144 samples. Of these, 0.64% (i.e., one sample) failed to meet DIS/TSS-12 microbiology requirements for total heterotrophic plate count, compared to an allowable failure rate of 15%. No spa water samples contained detectable levels of either enterococci or *E. coli*. The results of this study show that the *Spa Frog Mineral Cartridge* used with DCDMH as a source of free chlorine is effective in controlling total heterotrophic bacteria, enterococci, and *E. coli*. Control of these bacteria in spa water is observed at free chlorine concentrations of 1 ppm and higher. **For this reason the study supports the proposed label concentration of at least 1 ppm of free chlorine, when DCDMH is used with the Spa Frog Mineral Cartridge.**

VII. RECOMMENDATIONS

1. The submitted efficacy data (MRID 490522-01) support the use of the product, Spa Chlorine Disinfectant, as an effective disinfectant at a level of free chlorine of at least 1 ppm from DCDMH. The proposed label claims that the products, Spa Chlorine Disinfectant [Spa Cartridge] and Pool Frog Mineral Reservoir [Filter Spa Product], effectively destroy bacteria in spas when free chlorine levels are maintained ≥ 0.5 ppm. Field test data provided by the applicant support levels of ≥ 1 ppm free chlorine since mean level of free chlorine in Spa 1 and Spa 2 were 0.68 ppm and 0.80 ppm respectively. Label claims should be changed to indicate a use rate of at least 1 ppm free chlorine when DCDMH is used with the *Spa Frog Mineral Cartridge*.

2. Label claims of up to 75% reduction of free chlorine levels should be modified to reflect a minimum use rate of at least 1 ppm free chlorine.
3. In the proposed label language the applicant has referred to this product as a "sanitizer." Since "disinfection" claims are more stringent than "sanitizer" claims, it is recommended that the applicant use the word "disinfectant" rather than "sanitizer" on the label.
4. Label Page 12: The proposed label claims are unsubstantiated and imply that the product is effective without Spa Frog Mineral Cartridge:
SPA CHLORINE DISINFECTANT {boosts the concentration of} {super charges} FROG minerals for even greater effectiveness,
5. Since the product, Spa Chlorine Disinfectant, must be used in conjunction with a mineral spa system (in-line or floating) and is not intended for independent use, a clear statement of product requirements (and/or limitations) should be indicated in a prominent location on the label.